

TABLE 5

age at EDD	age risk	uncorrected UE MoM	risk assessment	
			uncorrected	corrected
15	1:1578	0.40	1:21	1:24
15	1:1578	1.00	1:3134	1:3246
30	1:909	0.50	1:17	1:14
30	1:909	1.00	1:1877	1:1870
45	1:28	0.40	1:1	2:1
45	1:28	1.00	1:64	1:58

Correction for the influence of maternal age on unconjugated estriol levels has a direct influence on the assigned risk for fetal Down Syndrome. A typical risk cut-off would be set at a risk of 1:250 as this approximately equals the risk of losing the baby through miscarriage as a result of the diagnostic amniocentesis. Depending upon the unconjugated estriol level and the mother's age the change could be sufficient for their risk to be altered from what would be considered high risk to low risk and vice-versa. Some typical examples of these changes are shown in Table 6.

TABLE 6

age at EDD	age risk	uncorrected UE MoM	Risk Assessment	
			Uncorrected	Corrected
30	1:909	0.58	1:239	1:256
35	1:384	0.70	1:281	1:241
40	1:112	1.00	1:252	1:230

A second consequence of such a correlation is that it would be expected to lead to a slight reduction in the overall variance of UE MoM, and a consequential decrease in the numbers of women who screen-positive with such a test.

The changes illustrated have occurred when using maternal age and unconjugated estriol as a screening test. The changes in risk-assessment as a consequence of the relationship between maternal age and unconjugated estriol will still be present even if further analytes are added to the risk assessment, such as AFP, hCG, the free beta or free alpha subunit of hCG, or any other maternal serum or fetal biometric marker for fetal abnormality.

Unconjugated estriol is also known to be a marker for Trisomy 18 and for anencephaly and similar arguments apply for the inclusion of a maternal age correction factor to the UE MoM when screening for those conditions.

The invention has been described in detail with particular reference to preferred embodiments thereof, but it will be understood that variations and modifications can be effected within the spirit and scope of the invention.

I claim:

1. An apparatus comprising:

a means adapted for receiving measurements of a pregnant woman's maternal blood concentration of unconjugated estriol its precursors, its metabolites, or a mixture thereof, and

a computer programmed to carry out the following activities:

A) determining a pregnant patient's prior risk of carrying a fetus having said chromosomal abnormality,  
B) calculating a normalized value of said concentration of unconjugated estriol its precursors, its metabolites, or a mixture thereof, by dividing by a median value found in a population of women with unaffected pregnancies with the same gestational age as said pregnant patient,

C) correcting said normalized value for influence of maternal age by dividing said normalized value by a corrected normal median value for a population of women of that maternal age,

D) calculating a first probability that the corrected normalized value is part of a Gaussian distribution of values found in pregnancies with said chromosomal abnormality,

E) calculating a second probability that the corrected normalized value is a part of a Gaussian distribution of values found in unaffected pregnancies,

F) calculating a likelihood ratio, said likelihood ratio being the ratio of said first probability and said second probability, and

G) modifying said prior risk by the likelihood ratio.

2. A method for antenatal risk assessment for a chromosomal abnormality in a fetus, comprising:

A) calculating a pregnant patient's prior risk of carrying a fetus having said chromosomal abnormality,

B) measuring said pregnant patient's blood for a concentration of unconjugated estriol, its precursors, its metabolites, or a mixture thereof,

C) calculating a normalized value of said concentration by dividing by a median value found in a population of women with unaffected pregnancies with the same gestational age as said pregnant patient,

D) correcting said normalized value for influence of maternal age by dividing said normalized value by a corrected normal median value for a population of women of that maternal age,

E) calculating a first probability that the corrected normalized value is part of a Gaussian distribution of values found in pregnancies with said chromosomal abnormality,

F) calculating a second probability that the corrected normalized value is a part of a Gaussian distribution of values found in unaffected pregnancies,

G) calculating a likelihood ratio, said likelihood ratio being the ratio of said first probability and said second probability, and

H) modifying said prior risk by the likelihood ratio.

3. The method according to claim 2, wherein said chromosomal abnormality is selected from the group consisting of Down Syndrome, Trisomy 18, Trisomy 13, and Turner Syndrome.

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